UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

Outsourcing Facilities Association, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendants, and Eli Lilly and Company, Intervenor-Defendant.	Case No. 4:24-cv-00953-P

Brief in Support of Federal Defendants' Motion for Summary Judgment

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INTRODUCTION

Congress authorized the Food and Drug Administration (FDA) to determine whether a drug is "in shortage in the United States." FDA's determination of a drug shortage triggers a variety of statutory mechanisms designed to alleviate the shortage and provide additional flexibilities to mitigate the disruption the shortage may cause. One such mechanism involves compounded drugs—medications that FDA does not approve or evaluate for safety, effectiveness, or quality before they are marketed.

Ordinarily, the Federal Food, Drug, and Cosmetic Act (FDCA) restricts the compounding of drugs that are essentially copies of FDA-approved drugs. When FDA determines that there is a nationwide shortage of a particular drug, however, the FDCA allows, during the shortage, certain compounding that it would otherwise restrict. Correspondingly, once FDA finds the shortage no longer exists, the FDCA's temporary allowance of such compounding ends.

In 2022, FDA deemed tirzepatide injection products—approved drugs manufactured and marketed by Eli Lilly and Company (Lilly) under the names Mounjaro (for type 2 diabetes) and Zepbound (for obesity and sleep apnea)—to be in shortage. The FDCA thus stopped restricting certain compounding of tirzepatide injection products. But in December 2024, after considering evidence from multiple sources—including data provided by Lilly and information submitted by Plaintiffs and individual patients and pharmacies—FDA determined that the shortage was resolved. To avoid disrupting ongoing patient treatment and promote an orderly transition, FDA also announced that it would temporarily not take action against compounders for certain violations of the FDCA. That period ended in March 2025.

Plaintiffs, a trade association for drug compounders and a pharmacy engaged in compounding, challenge the factual and legal bases for FDA's December 2024 determination that the shortage is resolved. None of their objections has merit.

FDA applied the plain meaning of the statute to determine whether a nationwide shortage existed. It reasonably credited evidence from Lilly showing that the company was fulfilling all orders while maintaining a surplus of [redacted]. FDA

also considered the available information from compounding pharmacies and determined that Lilly's supply of [redacted] exceeded even a generous estimate of the compounders' production. And as the Court recognized in its decision denying Plaintiffs' motion for a preliminary injunction, it was not unreasonable for FDA to give more weight to specific, reliable, comprehensive, and current information from Lilly than to anecdotal evidence from compounders and others.

FDA's decision was also procedurally proper. As a general matter, an agency has discretion to choose whether to proceed by rulemaking or adjudication. The statutory authority at issue here and the facts of this case left FDA with only one viable option: adjudication. The FDCA requires that the agency keep the shortage list "up-to-date," prohibits the agency from publicly disclosing the vast majority of information considered for its determinations, and authorizes FDA to keep confidential even the existence of its decision. The agency reasonably found those requirements were incompatible with notice-and-comment rulemaking and so proceeded by adjudication.

And FDA's decision fits squarely within the scope of an adjudication under the Administrative Procedure Act (APA). Unlike a rule, it did not establish any new law or policy that applies only prospectively. Instead, it resolved a discrete controversy by applying the statutory definition of "shortage" to a particular set of facts about the supply and demand of tirzepatide injection products. Moreover, because the decision is a declaratory order (rather than a legislative rule), it was not necessary for FDA to publish the decision in the Federal Register.

For these reasons, the Court should enter summary judgment for Federal Defendants.

BACKGROUND

I. Statutory background

A. FDA's regulation of drug manufacturing

The FDCA generally prohibits the introduction of a "new drug" into interstate commerce without FDA approval. 21 U.S.C. § 355(a). To obtain FDA approval, a manufacturer usually must submit a new drug application (NDA). *Id.* § 355(b)(1). FDA approves such applications

only if it finds, based on the evidence before it, that the drug is safe and effective for its intended use under the conditions of use described in the drug's labeling. *Id.* § 355(c)(1)(A), (d). Once an NDA is approved, facilities producing the drug must comply with "current good manufacturing practice" (cGMP) requirements, which "assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports . . . to possess." *Id.* § 351(a)(2)(B); *see* 21 C.F.R. Parts 210, 211. An NDA approval has significant effects on third parties. For example, for certain new drug approvals, the statute prohibits approvals of other manufacturers' applications for drugs using the same active moiety for five years (often referred to as "exclusivity" for the first drug approved). *See* 21 U.S.C. § 355(c)(3)(E)(ii).

Drug compounding is generally "a process by which a pharmacist or doctor combines, mixes or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). Unlike FDA-approved drugs, compounded drugs do not "undergo[] FDA premarket review for safety, effectiveness, and quality." AR10. Compounding pharmacies and physicians ("503A compounders") whose drugs meet the conditions of 21 U.S.C. § 353a are not required to follow cGMP, among other things. Under 21 U.S.C. § 353b, on the other hand, outsourcing facilities ("503B compounders") are subject to, among other things, cGMP, registration, and product reporting requirements, but like 503A compounders, the drugs they manufacture do not undergo FDA premarket review for safety, effectiveness, and quality.

Of particular importance here, the FDCA restricts production of compounded drugs that are "essentially a copy" of an FDA-approved drug, for both types of compounders. 21 U.S.C. §§ 353a(b)(1)(D), 353b(a)(5). This statutory restriction "works to protect the new drug approval process and, by extension, provides a market advantage to FDA-approved drugs" over compounded drugs. *Athenex Inc. v. Azar*, 397 F. Supp. 3d 56, 71 (D.D.C. 2019). But certain restrictions that typically apply to compounding copies of an approved drug are temporarily

lifted when the drug appears on the drug shortage list. *See* 21 U.S.C. §§ 353a(b)(1)(D), 353b(a)(5).

B. Drug shortages

The FDCA defines a "drug shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." 21 U.S.C. § 356c(h)(2). Congress requires FDA to "maintain an up-to-date list of drugs that are determined by [FDA] to be in shortage in the United States." *Id.* § 356e; *see* 21 C.F.R. § 314.81(b)(3)(iii)(*f*) (adopting the definition of "shortage" from 21 U.S.C. § 356c(h)(2)). Because FDA must consider drug manufacturers' confidential commercial information and trade secrets to determine whether a drug is in shortage, Congress provided that "[n]othing in this section alters or amends" 18 U.S.C. § 1905 or 5 U.S.C. § 552(b)(4), which collectively protect such information from disclosure. 21 U.S.C. § 356e(c)(2). Furthermore, Congress empowered FDA to "choose not to make information collected under this section publicly available" if doing so would "adversely affect the public health," such as where disclosing the information would "increas[e] the possibility of hoarding" the drug. *Id.* § 356e(c)(3).

When a drug appears on the shortage list, certain restrictions on compounding copies of the approved drug are temporarily lifted. As relevant here, the limitation on 503B compounders producing a drug that is "identical or nearly identical" to an approved drug does not apply. *Id.* § 353b(a)(5), (d)(2)(A); *see also id.* § 353b(a)(2)(A)(ii) (exemption from limitation on compounding using bulk drug substances). Also, the limitation on 503A compounders producing "drug products that are essentially copies" of approved drugs "regularly or in inordinate amounts" does not apply to drugs on the shortage list because FDA considers those drugs not "commercially available." *Id.* § 353a(b)(1)(D).

II. Factual and procedural background

In May 2022, FDA approved Lilly's NDA for Mounjaro. *See* FDA App. 4.[1] Under 21 U.S.C. § 355(c)(3)(E)(ii), FDA generally may not approve an NDA for a drug product containing tirzepatide as its active moiety from any other manufacturer until 2027. Due to high demand for Mounjaro that exceeded nationwide supply, FDA added it to the drug shortage list in December 2022. FDA App. 4. FDA approved Lilly's NDA for Zepbound in November 2023 and for the same reason added it to the drug shortage list in April 2024. *Id.*[2]

FDA initially declared the shortage resolved on October 2, 2024. Shortly thereafter, Plaintiffs challenged that decision and, on October 8, 2024, moved for a preliminary injunction. ECF Nos. 1, 7. Three days later, Federal Defendants moved to voluntarily remand this case to the agency for reevaluation. ECF No. 27. Federal Defendants made clear that Plaintiffs could submit additional information regarding tirzepatide's availability for FDA's consideration. *Id.* at 4. The Court granted Federal Defendants' motion and stayed proceedings. ECF No. 28.

On December 19, 2024, FDA issued a declaratory order finding that the shortage of tirzepatide was resolved.[3] After review of "detailed information and data regarding" Lilly's production and inventory of the drugs "at various points in time," FDA determined that Lilly was meeting or exceeding current demand for the products. FDA App. 2. Moreover, FDA found that Lilly had "developed reserves" of "finished product" and "significant units of semi-finished product," and that Lilly had plans for "substantial additional production" in the near future. *Id.* As such, FDA concluded that Lilly's "supply will meet or exceed projected demand." *Id*.

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[1] Citations to "FDA App." are to excerpts of the administrative record in this case, *see* ECF No. 76 (certified index to administrative record), and are provided in an appendix to this brief.

[2] For simplicity, the term "tirzepatide" in this brief refers to the products declared to be in shortage in December 2022 and April 2024, but not other tirzepatide products that have not been declared to be in shortage.

[3] The December 19, 2024 declaratory order "revokes and replaces FDA's October 2, 2024 decision on the same subject." FDA App. 1.

In addition to data from Lilly, FDA also considered information from "patients, healthcare providers, and others, including compounders, along with data from other sources that [FDA] independently identified." FDA App. 2. However, this information "ha[d] important limitations" and "[did] not undermine or outweigh" Lilly's evidence that its supply was currently meeting or exceeding demand and would also likely meet or exceed projected demand. *Id*. FDA thus declared the shortage of tirzepatide injection products resolved. FDA App. 12. FDA also announced temporary enforcement discretion for certain violations of the FDCA relating to compounding tirzepatide injection products. *See* FDA App. 3. The Declaratory Order was supported by a decision memorandum laying out in detail the agency's analysis and conclusions. *See* FDA App. 13–44.

In January 2025, Plaintiffs filed an amended complaint, ECF No. 68 (Am. Compl.) and a motion for a preliminary injunction, ECF No. 64, which the Court denied on March 5, 2025, ECF No. 100 (PI Order). The parties now file cross-motions for summary judgment.

LEGAL STANDARDS

In an APA case, the court reviews whether the challenged action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "Judicial review under that standard is deferential," *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021), "narrow," *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983), and based solely on the administrative record, *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam). "A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Prometheus Radio Project*, 592 U.S. at 423. In so doing, a court may not "substitute its judgment for that of the agency," *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), but must instead uphold the agency's action if it is "rational, based upon consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute," *State Farm*, 463 U.S. at 42.

ARGUMENT

I. FDA reasonably determined that the shortage was resolved

In December 2024, the question before FDA was whether Lilly's tirzepatide products still were "in shortage in the United States." 21 U.S.C. § 356e(a). Because the statutory provision creating the shortage drug list does not itself define a "shortage," FDA borrows the definition from a related provision. *See Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560, 566 (2012) (examining whether statutory term is defined in the particular provision "or in any other relevant statutory provision"). A "shortage" is "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." 21 U.S.C. § 356c(h)(2); 21 C.F.R. § 314.81(b)(3)(iii)(*f*) (adopting that definition for purposes of the drug shortage list). Thus, to determine whether tirzepatide was in shortage, "FDA evaluate[d] the supply and demand or projected demand of the drug on a nationwide level, across the entire market, not at the local level." FDA App. 15. This interpretation, giving effect to "the plain, obvious and rational meaning of" 21 U.S.C. § 356e, "is always to be preferred." *Lynch v. Alworth-Stephens Co.*, 267 U.S. 364, 370 (1925) (quotation omitted).

Plaintiffs assert that demand for compounded products should be considered part of the current demand for Lilly's products. Am. Compl. ¶ 101. But if a compounded product becomes part of the demand for the drug, it necessarily follows that the compounded product becomes part of the supply of the drug, and vice versa. Thus, following Plaintiffs' theory to its logical conclusion, the moment the supply of both the compounded and approved drug met overall demand, FDA would declare the shortage over and compounding would be curtailed. *See* 21 U.S.C. §§ 353a(b)(1)(D), 353b(a)(5), 353b(d)(2)(A), 353b(a)(2)(A)(ii). And without that compounded product on the market to meet some of the demand, it would *immediately* create a new shortage—a cycle that would continue indefinitely. *See* FDA App. 34–35 n.103. Congress clearly did not intend this absurd result. *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) ("[I]nterpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available.").

Equally misplaced is Plaintiffs' argument that FDA "ignore[d]" patients' inability to fill their prescriptions and did not consider "supply chain disruptions" to be "evidence" of a shortage. Am. Compl. ¶ 100 (Count Five). As a factual matter, FDA considered the available information on patient access and supply chain disruptions. *See* FDA App. 28–41. It simply concluded that other, more reliable evidence outweighed it and demonstrated the shortage had ended. *Cf. Prometheus Radio Project*, 592 U.S. at 426 ("The FCC did not ignore the Free Press studies. The FCC simply interpreted them differently."). And "disagreement by itself is insufficient to demonstrate that [FDA] failed to examine the relevant data and articulate a satisfactory explanation for its action." *AT&T Servs., Inc. v. FCC*, 21 F.4th 841, 851 (D.C. Cir. 2021).

Plaintiffs also allege that the Declaratory Order was arbitrary and capricious because it failed to "examine the relevant data," identify a "rational connection between the facts and the choice made," or address "the most basic parameters of its analysis." Am. Compl. ¶¶ 80, 83 (Count Two); *see id.* ¶¶ 85–95 (Counts Three and Four). The record shows otherwise. FDA thoroughly considered a host of data provided by Lilly and other sources (including Plaintiffs), reasonably found that "[Lilly's] supply [was] currently exceeding demand and [would] meet or exceed projected demand across all strengths of Mounjaro and Zepbound," and thus permissibly concluded that the shortage was resolved. FDA App. 17.

With respect to current demand, FDA first examined Lilly's stock reports (data on Lilly's inventory and orders for its tirzepatide products, broken down by dosage strength), and found that they "demonstrate[d] that Lilly ha[d] been filling wholesale orders as they [were] received while generally maintaining product in inventory net of open orders." FDA App. 17; *see* FDA App. 45–113, 132–213. Lilly explained that "it does not—and has not—limited the ability of any wholesaler to place orders for any quantities" of its tirzepatide products. FDA App. 17, 174. While Lilly reported [redacted]. FDA App. 17–19, 209. In addition,

Lilly's data showed that it had on hand over [redacted] doses of semi-finished products—products that were manufactured but not yet labeled or packaged—which FDA found "provide[d] assurance that Lilly will continue to be able to fill orders as they are received." FDA App. 18.

Separately and in addition to Lilly's inventory data, Lilly's data on cumulative supply and demand further demonstrated that cumulative supply for Mounjaro and Zepbound by the [redacted] had exceeded demand for all dosages by [redacted] doses. FDA App. 19–22, 208. Finally, FDA found that wholesale distributors and retail pharmacies had additional inventory on hand, beyond the inventory already accounted for in Lilly's possession. FDA App. 23–25, 171–74. And [redacted] FDA App. 23, 172. As such, FDA reasonably found that "taken as a whole," the data Lilly submitted supported the conclusion that supply was currently meeting or exceeding demand. FDA App. 27.

FDA also reasonably concluded that Lilly's supply would meet or exceed projected demand. As FDA explained, Lilly projected demand based on [redacted], among other factors. FDA App. 25, 146. Lilly's supply projections were based on [redacted]. FDA App. 25 n.53, 144, 146. Lilly projected that, [redacted]. FDA App. 27, 208. FDA noted that [redacted]. FDA App. 26 (comparing FDA App. 162 and FDA App. 191). FDA thus concluded that, "based on our best judgment looking at the available information with its limitations, [Lilly] will meet or exceed projected demand across all strengths of Mounjaro and Zepbound." FDA App. 27.

FDA also considered supply- and demand-related information from a variety of other sources, including Plaintiffs and individual patients and pharmacies, as well as news articles and blog posts, comments submitted to FDA's compounding docket, and reports of high volume of demand for compounded tirzepatide. FDA App. 28–35. This information included, for example, submissions regarding individual patients' inability to access Mounjaro or Zepbound, FDA App. 28–31, and screenshots from wholesalers' websites indicating that Mounjaro or Zepbound products were out of stock or limited in the amount that could be ordered, FDA App. 31–33.

The agency "carefully evaluat[ed] this information" but determined that it had "important limitations," FDA App. 14, and thus "[did] not undermine or outweigh . . . the detailed quantitative picture of the supply and demand situation both over time, and at the national level," that Lilly's data provided, FDA App. 31 (patient reports); *see also* FDA App. 32–34 (similar conclusions for each category). For example, many submissions from individual patients had no indication of *when* the patient had trouble accessing tirzepatide products. Nor did these reports use any consistent definition for what it meant to have trouble accessing a drug—a nebulous concept that could encompass, for many of the reports, not just an out-of-stock prescription, but also an inability to get a prescription from a doctor or an inability to get insurance coverage for the drug. FDA App. 29–30. Moreover, FDA credited Lilly's explanations that gaps in availability at individual pharmacies were likely caused by the "practical dynamics" of the supply chain between Lilly's production and the end user, rather than a national shortage of the products. FDA App. 30, 117. FDA similarly reasoned that the same dynamics most likely explained the screenshots of wholesalers' websites that purported to indicate that wholesalers were restricting sales of Lilly's products or that they lacked inventory. FDA App. 31–33. Further, given the significant limitations of the screenshot evidence, and Lilly's explanations, FDA concluded that "the screenshots do not provide reliable evidence in assessing whether supply of Mounjaro and/or Zepbound is meeting demand." FDA App. 33.

FDA also considered potential future increased demand from some patients receiving compounded tirzepatide switching to use of Lilly's product. The agency "recognize[d] that

significant compounding of tirzepatide injection products is occurring, and that some patients currently receiving those products can be expected to seek Lilly's approved products at a future point when compounding is curtailed." FDA App. 39. As FDA explained, there was limited information available about the volume of products that compounders were producing. FDA App. 36–38. But the agency acknowledged the limitations of the data, made conservative assumptions for purposes of its decision (*e.g.*, by assuming that submitted numbers were accurate and adding all available estimated volumes together), and noted that even the most generous estimate the agency could make of the total volume compounded "would represent a very small amount" compared to Lilly's supply of over [redacted] per month and substantial finished and semi-finished product inventory. FDA App. 24. FDA also observed that some patients receiving compounded tirzepatide would not start treatment with Lilly's products for a variety of reasons, including that Lilly's products were significantly more expensive than the compounded products. FDA App. 38–39. FDA thus reasonably predicted, based on the information available, that Lilly's supply would be able to accommodate any increased demand from patients currently receiving a compounded product and that the information from other sources "does not alter [its] conclusions" regarding Lilly's ability to meet current and projected demand. FDA App. 28; *see Prometheus Radio Project*, 592 U.S. at 427 (upholding agency's "reasonable predictive judgment based on the evidence it had").

In denying Plaintiffs' motion for a preliminary injunction, this Court recognized the reasonableness of FDA's decision. For example, while Plaintiffs had argued that FDA was required to identify and analyze a single precise window of time to find a shortage resolved, *see* Am. Compl. ¶ 82 (Count Two), the Court noted that FDA had "sufficiently identified what time period it considered in making the shortage determination." PI Order 18. Indeed, the statute does not require FDA to analyze a particular period of time, and FDA properly kept the "list of drugs" it "determine[d] to be in shortage" "up-to-date," 21 U.S.C. § 356e(a), by finding that the "period of time" when supply of tirzepatide failed to meet demand was over, *id.* § 356c(h)(2).

Similarly, while Plaintiffs alleged that FDA's decision was "based solely (or primarily) on statements by the manufacturer that it can meet demand, despite substantial probative evidence proving to the contrary," Am. Compl. ¶ 94 (Count Four), the Court rightly disagreed. It recognized that it was "not unreasonable for the FDA to give more weight to specific, reliable, comprehensive, and current information from Lilly" than it gave to other sources that "lacked the same detailed data." PI Order 26. Further, the Court observed that FDA "did not blindly rely on Lilly's assertions and evidence" but instead "scrutinized and rejected some of Lilly's evidence based on the same standards it applied to the countervailing evidence." PI Order 24 n. 12.

In sum, FDA applied the plain statutory meaning to the evidence before it and arrived at a well-reasoned decision. "The APA requires no more." *Prometheus Radio Project*, 592 U.S. at 427; *see Dep't of Com.v. State of New York*, 588 U.S. 752, 777 (2019) ("It is not for us to ask whether his decision was 'the best one possible' or even whether it was 'better than the alternatives.'") (quoting *FERC v. Elec. Power Supply Ass'n*, 577 U.S. 260, 292 (2016)). Federal Defendants are therefore entitled to summary judgment on Counts Two, Three, Four, and Five.

II. FDA reasonably proceeded by declaratory order rather than rulemaking

FDA's shortage determination was a classic adjudication under the APA because it applied the statutory definition of "shortage" to resolve a discrete controversy. Contrary to Plaintiffs' allegations, FDA's determination was not a legislative rule that must go through notice-and-comment rulemaking. Am. Compl. ¶¶ 69–78 (Count One). And because FDA's determination was not a legislative rule, it necessarily follows that Plaintiffs are also incorrect when they claim that the decision needed to be published in the Federal Register under 5 U.S.C. § 552(a)(1)(D). Am. Compl. ¶¶ 103–107 (Count Six). Federal Defendants are therefore entitled to summary judgment on those counts.

A. FDA properly issued a declaratory order

FDA properly issued its shortage determination through adjudication. Congress did not specify what procedure FDA must use to make shortage determinations. 21 U.S.C. § 356e.

Accordingly, under the default rule, the decision to proceed by adjudication rather than rulemaking "'is one that lies primarily in the informed discretion of the administrative agency,'" *McDonald v. Watt*, 653 F.2d 1035, 1042 (5th Cir. 1981) (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947)), and that decision is reviewable for an abuse of discretion, *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). An agency's judgment that there is "reason to . . . develop[] its standards in a case-by-case manner" with attention to the specific facts of each case "is entitled to great weight." *Id*.

FDA reasonably concluded that adjudication was the only viable option here for multiple reasons. FDA App. 5. First, Congress requires the list to be "up-to-date." FDA App. 8 (citing 21 U.S.C. § 356e(a)). The list must therefore "extend[] up to the present time" and "us[e] or includ[e] the latest facts." *Up-to-date*, Merriam-Webster New World College Dictionary (4th ed. 2009). For tirzepatide, FDA considered supply-and-demand data submitted throughout fall and winter 2024 to reach its shortage determination. *See* FDA App. 17 n.16. Even expeditious notice-and-comment rulemaking would not permit such timely action. FDA App. 8.

In denying Plaintiffs' motion for a preliminary injunction, the Court recognized that notice-and-comment rulemaking would inhibit FDA's performance of its statutory obligations as the time required for such rulemaking would prevent the shortage list from being "up-to-date." 21 U.S.C. § 356e(a). "Given the constant fluctuation in national supply and demand numbers for a given drug," the Court observed, "a rule based on data that is more than a month old cannot be said to be based on 'the latest information' available." PI Order 9–10. And if shortage resolution decisions required rulemaking, the Court explained, so must shortage listing decisions, and the "lengthy rule-making process" to add and subtract drugs from the shortage list "cannot be said to be congruent with Congress's mandate for the FDA to maintain an 'up-to-date list of drugs . . . in shortage in the United States.'" *Id.* at 10 (quoting 21 U.S.C. § 356e(a)).

Second, FDA could not engage in meaningful public notice-and-comment because Lilly maintained as confidential the core, material facts. To satisfy the APA's requirement that a proposed rule "give interested persons an opportunity to participate," 5 U.S.C. § 553(c), an

agency must "reveal[] for public evaluation" the "technical studies and data upon which the agency relies," and in particular, "the most critical factual material used by the agency," *Chamber of Com. v. SEC*, 443 F.3d 890, 899–900 (D.C. Cir. 2006) (internal quotations omitted). An agency therefore "commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary." *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991).

In the circumstances of this case, the most critical factual material was the manufacturer's confidential business information, all of which FDA is prohibited from disclosing. *See, e.g.*, 21 U.S.C. §§ 331(j), 356e(c)(2); 21 C.F.R. § 314.81(b)(2)(vii)(*b*). The agency also could not summarize that data in a way that allowed for meaningful public comment; only the agency's *conclusions* based on the data are disclosable. *See* ECF No. 67, Ex. 1, OFA PI Motion App. 17–49 (redacted decision memorandum). Consequently, FDA could not have issued a proposed rule to amend the shortage list that "reveal[ed] for public evaluation" the "most critical factual material" upon which the agency relied. *Chamber of Com.*, 443 F.3d at 899–900. As the Court correctly concluded, maintaining the confidentiality of Lilly's information while also providing the public meaningful opportunity to comment was an "unattainable" goal. PI Order 9 n.3.

Third, Congress also gave FDA the discretion to withhold information that is not confidential, including the very *existence* of a shortage. 21 U.S.C. § 356e(c)(3). The public-health exception authorizes FDA to "choose not to make information" on the shortage list public if it "determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients)." *Id*. That provision is fundamentally incompatible with public notice and comment. In at least those cases, FDA *must* proceed by adjudication.

Of the different types of adjudications under the APA, declaratory orders allow agencies to efficiently apply existing policy to a set of facts without the need for any particular party to risk penalty or sanction. 5 U.S.C. § 554(e); *see City of Arlington, Tex. v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012); *Qwest Servs. Corp. v. FCC*, 509 F.3d 531, 536–37 (D.C. Cir. 2007). Drug shortage

determinations, given their discrete nature and context, are well-suited to resolution through a declaratory order—as FDA did here. *See, e.g.*, *Am. Airlines, Inc. v. Dep't of Transp.*, 202 F.3d 788, 796–97 (5th Cir. 2000) (affirming agency's decision to issue a declaratory order through adjudication).

Although the "line between" adjudication and rulemaking "is frequently a thin one," *Gen. Am. Transp. Corp. v. Interstate Com. Comm'n*, 83 F.2d 1029, 1030 n.2 (D.C. Cir. 1989), FDA's shortage determination had none of the characteristics of a rule. The "basic distinction between" the two is that adjudications are "proceedings designed to adjudicate disputed facts in particular cases," whereas rulemakings are "proceedings for the purpose of promulgating policy-type rules or standards." *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 244–45 (1973); *see* 5 U.S.C. §§ 551(4) (defining "rule"), 551(6) ("order"), 551(7) ("adjudication"). FDA applied the statutory definition of shortage to "a particular set of disputed facts," *Fla. E. Coast Ry.*, 410 U.S. at 246—namely, to data demonstrating the current and projected nationwide supply and demand of tirzepatide, 21 U.S.C. § 356c(h)(2). The agency did the same thing in December 2022 to find there was a shortage. The difference in December 2024 was the evidence, demonstrating that FDA decided "each case upon individual grounds," *Fla. E. Coast Ry.*, 410 U.S. at 245 (citation omitted), and applied the law consistently on "a case-by-case" basis, *Bell Aerospace*, 416 U.S. at 291–94.

Moreover, FDA's findings about the availability of a particular drug as of the time of its decision are not "applicable across the board" nor "generalized [in] nature." *Fla. E. Coast Ry.*, 410 U.S. at 246. Nor were the agency's factual findings "used in the formulation of a basically legislative-type judgment." *Id.* And in contrast to the purely "prospective application" of a rule, *id.*, FDA's adjudication determined "present rights and liabilities" by finding that there was not *presently* a shortage, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 221 (1988) (Scalia, J., concurring) (quoting Attorney General's Manual on the APA 14 (1947)).

B. Any procedural error was harmless

Even if FDA's determination that the shortage was resolved should have been subject to notice and comment, any error would be harmless. *See* 5 U.S.C. § 706. If an agency errs by not following notice-and-comment procedures, the error is harmless if "the lack of notice and comment did not prejudice" plaintiffs. *City of Arlington*, 668 F.3d at 244. That is the case here.

As early as August 2024, through updates submitted to the agency's public drug shortages website, Lilly indicated that it believed the shortage had ended. *See* FDA App. 16 n.15. Two months after that, FDA notified the public about its initial determination through its website. FDA App. 8–9. FDA then openly solicited comment and data, ECF No. 27 at 4, and the public had more than two-and-a-half months to submit information. Though FDA was unable to disclose the most critical factual material, FDA "received and considered comments from" a variety of "interested parties," *City of Arlington*, 668 F.3d at 245, including from individual patients, pharmacy compounders, outsourcing facilities, trade associations, and telehealth companies, *see* FDA App. 14, 16–29. Plaintiffs were among the many commenters. *See*, *e.g.*, FDA App. 214–28 (comment from FarmaKeio, with attachments); FDA App. 229–61 (one of multiple comments from counsel for OFA, with attachments). Because Plaintiffs "received notice of the issues pending before [FDA] and had the ability to comment on [them] in the agency proceedings," and FDA already "considered and addressed" the issues raised in this litigation, Plaintiffs suffered no prejudice from a lack of notice and comment. *City of Arlington*, 668 F.3d at 245–46.

CONCLUSION

Summary judgment should be entered for Federal Defendants.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent by electronic mail to the registered participants as identified on the Notice of Electronic Filing.

April 2, 2025

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